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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,889	11/07/2001	Robert D. Black	9099-4	7939
20792	7590	02/07/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC				COUNTS, GARY W
PO BOX 37428				ART UNIT
RALEIGH, NC 27627				PAPER NUMBER
				1641

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,889	BLACK, ROBERT D.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 December 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8-17 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8-17 and 29-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/27/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of the claims

The amendment filed December 27, 2004 is acknowledged and has been entered.

Rejections Withdrawn

The objection to the specification is withdrawn in view of the amendments to the claims and the specification.

The objection to claim 13 is withdrawn in view of the amendment to the claim.

The rejections of claims 9 and 16 as being vague and indefinite is withdrawn in view of the amendments to the claims. Further, applicant's deletion of the phrase "via the inductor" makes it clear that the inductor provides power to the circuit. Therefore, the following new ground(s) of rejection is applied to claim 14 (see 103 rejection below).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 15 lines 18-19 in the specification the applicant discloses the lifetime of the implant may be as long as six months or even more in some cases. The specification does not disclose the circuit comprises a

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chronically implantable. There is no description in the specification disclosing that the circuit comprises a chronically implantable.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30, line 2 the recitation "chronically implantable" is vague and indefinite. It is unclear what applicant intends. There is no definition provided for the term in the specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs et al (US 5,833,603).

Kovacs et al disclose a circuit comprising Light emitting diodes (LED's) (optical radiation source), a photosensor (optical radiation detector) and control circuitry (col 5,

lines 1-27, col 11, line 44 – col 12, line 33). Kovacs et al disclose that this circuit can be configured for in vivo detection. Kovacs et al disclose that the photosensor can be photodiodes or phototransistors (col 2, lines 25-30).

With respect to the recitation "optical radiation emitted by excited labeled binding molecules" as recited in the instant claims. Since Kovacs et al teach the same circuit as recited, the circuit of Kovacs is capable of detecting excited labeled binding molecules and therefore, Kovacs anticipates the claims.

7. Claims 8, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini, Jr. et al (US 6,551,838).

Santini, Jr. et al. disclose a circuit for in vivo applications. Santini, Jr. et al. disclose the circuit comprises a fiber optic which emits light (optical radiation source). Santini, Jr. et al also discloses that the fiber optic can detect and measures changes (optical radiation detector) in fluorescence or some other optical phenomenon. Santini, Jr. et al disclose control circuitry coupled to the fiber optic (col 9, lines 54-67, col 15, line 59 – col 16, line 43 and Figure 7). Santini, Jr. et al disclose coating or encapsulating all components of the circuit in a biocompatible material such as polyethylene glycol or metal or ceramic (col 9, lines 47-51 and col 15, lines 47-51). Santini, Jr. et al disclose the circuit is on a backing plate (platform) (col 17). Santini, Jr. et al disclose the device can be the size of a millimeter (col 4, lines 35-36).

With respect to the recitation "optical radiation emitted by excited labeled binding molecules" as recited in the instant claims. Since Santini, Jr. et al teach the same

circuit as recited, the circuit of Santini, Jr. et al is capable of detecting excited labeled binding molecules and therefore, Santini, Jr. et al anticipates the claims.

With respect to newly added claims 29-33 since Santini Jr. et al disclose the same structures as recited in the instant claims and since Applicant has not recited any structural differences over Santini Jr. et al. The circuit of Santini Jr. et al is capable of performing the limitations of the recited claims and therefore, Santini Jr. et al anticipates the claims.

8. Claims 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Crowley (US 6,343,227).

Crowley teaches a circuit comprising a light source (optical radiation source) and a light detector (optical radiation detector). Crowley teaches that the light source illuminates a substance and the detectors detect optical properties of the illuminated substance by measuring modified light signals (col 2, lines 18-31) (Figure 1A). Crowley teaches the circuit comprises a modulator for modulating the light source and also comprises an analog to digital converter and a microprocessor for spectral analysis (col 3, lines 34-57). Crowley teaches the light source may be a light emitting diode and the light detector may be a photodiode (col 2, lines 44-50). Crowley teaches the light source may be coupled to a filter (col 9, lines 8-11). Crowley teaches the light detector may be coupled to a filter (col 5, lines 20-48, Fig. 2A and Fig. 4).

With respect to the first frequency is greater than the second frequency as recited in the instant claims. This limitation depends on the label that is used, and the label is not part of the circuit and therefore, whether or not the first frequency is greater

than the second frequency is irrelevant. Therefore, Crowley anticipates the instantly recited claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini Jr. et al in view of Sheppard, Jr. et al (US 2002/0072784).

See above for teachings of Santini Jr. et al.

Santini Jr. et al differ from the instant invention in failing to teach an inductor coupled to the processor (page 5, paragraph 0055 and Figure 1).

Sheppard Jr. et al. disclose an inductor coupled to a processor. Sheppard Jr. et al discloses that this inductor provides for devices, systems and methods for wirelessly powering and/or communicating with microchip devices used for the controlled exposure and release of reservoir contents (abstract). Sheppard Jr. et al also teaches

that this provides for devices for reducing or eliminating the need for pre-charged power sources and provides avoiding explantation of implanted microchip devices for the purpose of replacing or recharging the devices power source or for the purpose of reprogramming the devices' microprocessor and also provides additional means for powering and communicating with microchip devices (page 1, paragraphs 0007-0009).

It would have been obvious to one of ordinary skill in the art to incorporate an inductor such as taught by Sheppard Jr. et al into the processor of Santini Jr. et al because Sheppard Jr. et al teaches that this inductor provides for devices, systems and methods for wirelessly powering and/or communicating with microchip devices used for the controlled exposure and release of reservoir contents (same type of device as disclosed in Santini Jr. et al.) and further because Sheppard Jr. et al also teaches that this provides for devices for reducing or eliminating the need for pre-charged power sources and provides avoiding explantation of implanted microchip devices for the purpose of replacing or recharging the devices power source or for the purpose of reprogramming the devices' microprocessor and also provides additional means for powering and communicating with microchip devices.

Response to Arguments

12. Applicant's arguments filed December 27, 2004 have been fully considered but they are not persuasive.

Applicant argues that Kovacs does not disclose and "optical radiation detector that is configured to detect second optical radiation emitted by excited labeled-binding molecules"

and that the dye-based sensors in Kovacs do not necessarily disclose or (inherently disclose) the specific recitation of claim 8 which focuses on the specific configuration "to detect second optical radiation emitted by excited labeled-binding molecules. This is not found persuasive because this is intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, since Kovacs et al teaches the same structures as instantly recited the structural limitations have been met and Kovacs reads on the instantly recited claims.

Applicant argues that Kovacs does not disclose transmitting " a signal associated with the intensity of the second optical radiation to an ex vivo system" as Kovacs appears to discuss transmitting a change in the optical properties to another system, not transmitting a signal associated with the intensity of the second optical radiation to an ex vivo system as recited in independent Claim 8. This is not found persuasive because this is intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*,

152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, since Kovacs et al teaches the same structures as instantly recited the structural limitations have been met and Kovacs reads on the instantly recited claims.

Applicant argues that Santini does not disclose, at least, "an optical radiation detector configured for in vivo use that detects second optical radiation emitted by excited labeled-binding molecules" and a processor circuit that transmits "a signal associated with the intensity the second optical radiation to an ex vivo system." This is not found persuasive because Santini teaches the same structures as instantly recited and therefore the circuit of Santini is capable of use for detection of second optical radiation emitted by excited labeled-binding molecules and is also capable of transmitting a signal associated with the intensity the second optical radiation to an ex vivo system. Applicant has not recited any structural differences for achieving this intended use of the circuit. Therefore, since Santini Jr. et al teaches the same structures as instantly recited the structural limitations have been met and Santini Jr. et al. reads on the instantly recited claims.

Applicant argues that Crowley does not disclose, at least, "an optical radiation detector configured for in vivo use that detects second optical radiation emitted by excited labeled-binding molecules" and a processor circuit that transmits "a signal associated with the intensity the second optical radiation to an ex vivo system." This is not found persuasive because Crowley teaches the same structures as instantly recited and therefore the circuit of Crowley is capable of use for detection of second optical radiation emitted by excited labeled-binding molecules and is also capable of transmitting a signal associated with the intensity the second optical radiation to an ex vivo system. Applicant has not recited any structural differences for

achieving this intended use of the circuit. Therefore, since Crowley teaches the same structures as instantly recited the structural limitations have been met and Crowley reads on the instantly recited claims.

Applicant argues that new claims 29-33 are patentable over the cited references. This is not found persuasive because new claims 29-33 do not incorporate any different structural features to distinguish them from the prior art of record and further, because the prior art teaches the same structures as recited in the instant claims and therefore are capable of performing the intended uses as recited (see rejections above concerning claims 29-33).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
January 26, 2005



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02/02/05